Attachment B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ADMIN PROCEEDINGS STAFF
1986 MAY -9 PM 1:55

MAY 8 1986

Roxane Laboratories
Attention: Donald H. Chmielewski, R.Ph.
P.O. Box 16532
Columbus, OH 43216-6532

Docket No. 86P-0161/CP

Dear Mr. Chmielewski:

This is in response to your petition filed April 14, 1986 requesting permission to file Abbreviated New Drug Applications (ANDA's) for the following drug products: Acetaminophen 500 mg and Codeine Phosphate 15 mg, 30 mg or 60 mg Tablets. The listed drugs to which you refer are Tylenol with Codeine #2, #3 and #4 (acetaminophen 300 mg and codeine phosphate 15 mg, 30 mg, and 60 mg) Tablets.

We have carefully reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), and have determined that it is approved. This letter represents the Agency's determination that the above-referenced products are suitable for submission as an ANDAs.

Your request involves a change in strength, i.e., from 300 mg to 500 mg of the acetaminophen component of the drug product. The type of change you propose is the type of change authorized under Section 505(j)(2)(C) of the Act.

Under Section 505(j)(2)(C)(i) of the Act the Agency must approve a petition seeking a change in strength from the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

Since the proposed change in strength of the acetaminophen component falls within acceptable limits established by the Monograph for OTC Internal Analgesics, Antipyretic and Antirheumatic Products, the Agency has determined that the proposed change in strength does not pose questions of safety or effectiveness, and concludes, therefore, that investigations are not necessary in this instance.

The approval of this petition to allow ANDAs to be submitted for the above-referenced products does not mean that the Agency has determined that ANDAs will be approved for the products. The determination that ANDAs will be approved is not made until the ANDAs themselves are submitted and reviewed by the Agency.

To permit review of your ANDA submission you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved the products will, among other things, be required to meet current bioequivalence requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you contact the Director, Division of Bioequivalence at (301) 443-0181 to determine the specific requirements for these products. During the review of your applications, the Agency may require the submission of additional information.

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The listed drug product to which you refer in your ANDAs must be the one upon which you based this petition. In addition, you should refer in your ANDAs to the petition docket number above, and include a copy of this letter in each ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, HFA-305, Room 4-62.

Sincerely yours,

Peter H. Rheinstein, M.D., J.D., M.S.
Director, Office of Drug Standards
Center for Drugs and Biologics